DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

June 5, 2002

VIA FEDERAL EXPRESS – NEXT DAY

Mr. Stanley Hall, Owner
Hall & Hall Farm
Old Snapps Ferry Road
Limestone, TN 37681

Warning Letter No. 02-NSV-27

Dear Mr. Hall:

An inspection at your dairy farm located in Limestone, Tennessee, was conducted by our investigator on April 24, 2002. That inspection confirmed that you offered a cow for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you may have caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act. You can find this Act and associated regulations through links on FDA's home page at www.fda.gov.

On or about August 22, 2001, you sold a cow, identified by U.S. Department of Agriculture (USDA) sample number 424954 and back tag number 63AB8714 for slaughter as human food at [redacted] to [redacted], through [redacted], and [redacted]. USDA analysis of tissue samples collected from that cow identified the presence of 3.88 parts per million (ppm) gentamicin in the kidney tissue. There is no established tolerance for gentamicin in cattle (Title 21, Code of Federal Regulations (21 CFR) 556.300). The presence of this drug in the edible tissue from this animal causes the food to be adulterated.

Our investigator also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals have been treated only with drugs which have been approved for use in those animal species and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissue. Foods from animals held under such conditions are adulterated.

You are adulterating the drug gentamicin within the meaning of Section 501(a)(5) of the Act when you fail to use the drug in conformance with the approved labeling. Gentamicin is not approved for use in dairy cattle. Use of this drug contrary to the approved conditions of use may only be done when a veterinarian is involved in the decision based on a valid veterinarian/client/patient relationship, no residue occurs, and the conditions described in 21 CFR Part 530, Established Drug Use in Animals, has been met.

This letter may not list all the deviations at your farm. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your farm into compliance with the law. Your response should include each step taken to correct the violations and prevent their recurrence. If you cannot complete corrections within 15 working days, we expect you to explain the reason for the delay and state when any remaining deviations will be corrected. Please include copies of any documentation demonstrating that corrections have been made.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Carl E. Draper

Carl E. Draper
Director, New Orleans District

CED:JEH:man

Enclosures:
21 CFR 530
21 CFR 556.300